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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/619,454	07/16/2003	Cheryl Fitzer-Attas	20555/1203432-US1	7700
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DARBY & DARBY P.C. P.O. BOX 770 Church Street Station New York, NY 10008-0770			EXAMINER STANDLEY, STEVEN H	
			ART UNIT 1649	PAPER NUMBER
			MAIL DATE 10/09/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/619,454

Applicant(s)

FITZER-ATTAS ET AL.

Examiner

Steven H. Standley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 September 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38, 42, 46 and 48-59 is/are pending in the application.
- 4a) Of the above claim(s) 1-36, 47 and 49-59 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 37, 38, 42, 46 and 48 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>12/06&9/06</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

The amendment filed 6/27/07 has been made of record. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

Claims 1-36, 47, and 49-59 were withdrawn in the prior action. Claims 39-41, and 43-45 have been cancelled by applicant. It is noted that applicant has indicated claim 42 is cancelled on page 42 of remarks. However, it appears to be amended on page 11 of the claims.

Claims 37-38, 42, 46, and 48 are under examination.

Objections/Rejections: Maintained/New Grounds

Specification

4. The examiner notes the applicant has inactivated hyperlinks in the specification. The objection is withdrawn by the examiner.

Claim Objections

5. The examiner notes the applicant has corrected claims 38 and 42 for minor claim objections. The objection is withdrawn by the examiner.

Claim Rejections - 35 USC § 112

Rejection of claims 37-38, 42, 46, and 48 under 35 USC § 112, 2nd paragraph, is withdrawn due to applicant's arguments.

Objections/Rejections: Maintained/New Grounds

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Rejection of claims 37-38, 42, 46, and 48 under 35 USC § 112, 1st paragraph, enablement is maintained for the reasons made of record in the office action dated 12/28/06. Applicant's arguments have been fully considered and not found to be persuasive. Applicant argues on pages 15 and 16 of Remarks dated 6/27/07 that the specification is enabling. The examiner has no issue with steps a. and b., however: 1) the preamble recites "a method of determining T-cell epitopes," and 2) it is accomplished in step c. by "comparing said resulting score to **a preselected value** that is indicative of the presence of a T-cell receptor epitope," which has no nexus to determining T-cell epitopes. The value does not determine T-cell epitopes. Furthermore, the state of the art with regard to predicting the reaction to a vaccine, or reducing the autoimmunity to a vaccine is unpredictable and practically non-existent. The art says predicting a t-cell response cannot be done. See Descotes et al. as cited in the prior office action. Applicant notes on page 19 that the claims are drawn to **predicting the probability of eliciting a T-cell response**. This is false. The claims are to "a method of determining T-cell epitopes..." This is not a probabilistic statement. It is absolute. The method absolutely determines T-cell epitopes. The examiner is

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saying applicant is not enabled for that. Furthermore, no rational basis for a "preselected value" being able to determine such has been disclosed.

8. Rejection of claims 37-38, 42, 46, and 48 under 35 USC § 112, 1st paragraph, written description is maintained for the reasons made of record in the office action dated 12/28/06. Applicant's arguments have been fully considered and not found to be persuasive. Applicant argues That Table 7 of Example 6 provides a "preselected value." The examiner notes that number is 49. The examiner acknowledges that applicant has provided the value '49' as a preselected value without any further teachings as to how the number was arrived at or what method underlies determining a "preselected value." Applicant has written description for the value "49" as a preselected value. And, from the specification, "14," and "60", and "74," and "22," and "45." However, applicant does not have written description as to how to determine the value.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 37-38, 42, 46, and 48 are rejected. Claims 37, 38 and 42 recite the limitation "a preselected value" in the final step. There is insufficient antecedent basis for this limitation in the claim. There is no step before wherein a value is selected or determined. Applicant argues that the amendment "that is indicative of the presence of

a T-cell epitope" obviates the rejection. This is not found persuasive because there is no step in which a value that is indicative of the presence of a T-cell epitope is determined.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 37 is rejected under 35 U.S.C. 102(b) as being anticipated by Parker et al (1994; in Applicant's IDS).

Parker et al determine epitopes within many peptides (see table VII) which are 'homologues' of a-geta by determining a binding value of each amino acid (see table V), determining the resulting score (table VII), and comparing the resulting score to a preselected value (see 'experimental value' in Table VII) to predict the presence of binding epitopes or 'T-cell epitopes.'

Applicant argues that the polypeptide of Parker is not an A-beta homologue because the specification requires the polypeptide have 70% identity with A-beta. However, the specification does not teach or limit the minimum or maximum length of the A-beta homologues, it merely requires 70% identity. Also, see example 6 in which shorter peptides of a-beta are used. Thus, A-beta sequence of SEQ ID NO: 144 shares

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100% homology over 4 amino acids with the fifth peptide down from the top of Parker et al. , Table 1, left column, page 165.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Steven Standley whose telephone number is **(571) 272-3432**. The examiner can normally be reached on Monday through Friday, 8:00 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on **(571) 272-0841**.

The fax number for the organization where this application or proceeding is assigned is **703-872-9306**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

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Steve Standley, Ph.D.

6/27/07



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SUPERVISORY PATENT EXAMINER
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